

Iowa Board of Pharmacy

October 25, 2022 Minutes

Members Present

Kathy Stone, Chair Gayle Mayer, Vice-Chair Bob Egeland Erik Maki Jim Mennen Dane Nealson Joan Skogstrom Sherill Whisenand

Staff Present

Andrew Funk, Executive Director Laura Steffensmeier, Assistant Attorney General Melissa Carstens, PMP Associate Administrator Amanda Woltz, Administrative Assistant

Compliance Officers

Curt Gerhold Mark Mather Britney Origer Maggie Phelps Jean Rhodes Jennifer Tiffany Jim Wolfe

Staff Absent

Mitchell Barnett, Associate Director of PMP Becky Carlson, Administrative Assistant Sue Mears, Compliance Officer

Call to Order

At 9:03 a.m., on Tuesday, October 25, 2022, Kathy Stone, called the meeting of the Iowa Board of Pharmacy to order.

Public Comment Period

None

Approval of Minutes

1. August 24, 2022 Open Session Minutes

Motion by Dane Nealson, second by Erik Maki, to approve the open session minutes of the August 24, 2022 meeting as presented. Motion passed unanimously.

Mandate for Electronic Transmission of Prescriptions

1. Richard Nightingale, MD

Motion by Erik Maki, second by Gayle Mayer, to approve the petition for exemption as submitted. Motion passed unanimously.

2. Women's Choice Center

Motion by Gayle Mayer, second by Dane Nealson, to approve the petition for exemption as submitted. Motion passed unanimously.

Requests

- 1. AlixaRx's Innovative Pharmacy Pilot Project Quarterly Report and Pilot Project Renewal Request
 - Motion by Gayle Mayer, second by Bob Egeland, to approve the renewal of the pilot project to July 2024 requiring reports every six months, instead of every meeting. Motion passed unanimously.
- 2. Request to waive 657 IAC 6.7(5)"b" requiring utilization of a video surveillance system no later than July 6, 2023 Central Iowa Compounding, Pharmacy license 762, Urbandale
 - Motion by Dane Nealson, second by Sherill Whisenand, to deny the request. Motion passed unanimously.
- 3. Request to waive 657 IAC 4.7 requiring a foreign pharmacy graduate candidate for licensure to obtain 1,500 hours of internship Eferonia Soliman, Pharmacist-intern registration 8249, Waukee
 - Motion by Jim Mennen, second by Dane Nealson, to approve the request to reduce the required internship hours by 500 hours. Motion passed unanimously.
- 4. Request to waive 657 IAC 17.3(1)"c" requiring evidence of Drug Distributor Accreditation as a condition for license renewal Americares Foundation, Wholesale Distributor license 6654, Stamford, CT
 - Motion by Sherill Whisenand, second by Dane Nealson to approve the request as submitted to December 31, 2025. Motion passed unanimously.
- 5. Request to waive 657 IAC 17.3(1)"c" requiring evidence of Drug Distributor Accreditation as a condition for licensure Padagis South Carolina, Wholesale Distributor license applicant, Piedmont, SC

Motion by Dane Nealson, second by Sherill Whisenand, to approve the request for six months. Motion passed unanimously.

Reports & Informational Items

1. Executive Director's Report

Staffing:

- After 18 years of dedicated service to the State and the Board of Pharmacy, compliance officer Jen Tiffany has resigned. Jen has spent a majority of her career with the Board as a compliance officer, but also served as the associate director of the PMP and played a critical role in implementing the state's opioid bill and new PMP technology.
- Britney Origer has joined the team as a compliance officer. Britney will be responsible for inspecting hospital pharmacies, compounding pharmacies, and veterinarian controlled substance registrants on the eastern side of Iowa.
- Interviews for the vacant licensing specialist position have been completed and a hiring decision will be made in the upcoming days.

Staff Anniversaries

• Compliance office, Maggie Phelps is celebrating one year of service with the Board.

Nominations, Appointments, Presentations

- Mitch Barnett is presenting the Board's PMP Data Validation project at the National Association of State Controlled Substance Authorities (NASCSA) October 26, 2022 in Salt Lake City, UT
- Director Funk will be presenting the Board's activities relating to pharmacy compounding at the virtual FDA Intergovernmental Working Meeting on Drug Compounding on Wednesday, November 2, 2022.
- Licensing Specialist Melanie Givens and IMP3 Coordinator Becky Carlson will be presenting the pharmacist licensure process and the Board's monitoring program to the University of Iowa's P4 on November 3, 2022.
- Director Funk will be presenting the Board's rules and intern responsibilities to the P1 class at Drake on November 11, 2022.
- Board member terms that are up in 2023:
 - o Gayle Mayer (up for third and final term)
 - o Sherill Whisenand (up for second term)
 - o Bob Egeland (up for second term. Bob assumed Brett Barker's appointment when he resigned in December 2021).

USP Revisions

• Updates to USP 795 and 797 will be posted on November 1, 2022. Compliance officers Jean Rhodes and Britney Origer will plan to evaluate those revisions and present them to the rules committee and ultimately the full Board. We will also plan a communication strategy to those licensees impacted by the revised standards. The effective date of the revisions will be 6 months after publication, or June 1, 2023.

Special Pharmacy Recognition

• Towncrest Pharmacy in Iowa City was recognized on a Federal Therapeutics Weekly Clinical Rounds call in September for its assistance with developing a <u>patient eligibility screening checklist tool</u> and for prescribing paxlovid under the PREP Act authority. As of October 14, pharmacists at Towncrest Pharmacy have prescribed over 100 courses of paxlovid.

2. Meetings and Travel

•	FDA Intergovernmental Working Meeting on Pharmacy Compounding.	November 1-2
•	IPA's Practice Act Task Force	November 8
•	Rules Committee	November16
•	ASHP Clinical Midyear	December 4-8
	Next Board meeting.	

3. **Legal Update**

Laura Steffensmeier provided an update regarding open cases. The Empower Pharmacy appeal has been transferred to the Court of Appeals and are awaiting to hear whether it will be set for an oral or non-oral case.

4. Prescription Monitoring Program (PMP) Update

Director Funk provided a program update.

PMP Integrations

•	In state chain pharmacies	307
	In state independent pharmacies	
	Nonresident pharmacies	
	Clinics/physician offices within Iowa	
	Clinics/physician offices outside of Iowa	
	Iowa hospitals	
	Hospitals outside of Iowa	
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Statewide Integration Initiative

• The Statewide Integration Initiative launched June 15, 2022. The initiative provides funding for a statewide PMP integration option that is available to Iowa prescribers and pharmacists. 97 new entities have signed up since it launched. Addition information concerning the Statewide Integration Initiative can be found at https://pharmacy.iowa.gov/prescription-monitoring-program.

Quarterly Prescriber Activity Reports

• 11,116 reports were sent this quarter.

Pharmacist Narcan® Dispensing Program

• From July 1, 2020 to September 30, 2022 the Pharmacist Narcan® Dispensing Program has had 4,433 fills with 4,227 unique patients.

Pharmacist Disposal Kit Dispensing Program

• From July 1, 2021 to September 30, 2022 the Pharmacist Disposal Kit Dispensing Program has had 19,000+ fills for 14,000+ unique patients.

5. Board-Sponsored Medication Disposal Update

Melissa Carstens provided a program update. According to the last report from the vendor Sharps, Inc., the program now has 312 permanent controlled substance receptacle sites in Iowa. Overall, the program has over 520 participating pharmacies (both controlled and non-controlled sites). This is a 1.2% increase and 0.5% increase respectively over a two-month time frame.

Pharmacies are able to install a smaller 18 gallon or larger 38 gallon DEA-compliant permanent receptacle, but we still provide liners for receptacles previously placed by prior vendors.

In August and September the program serviced 271 twenty-two gallon, 39 twenty gallon, 3 eighteen gallon, and 18 thirty-eight gallon liners. The program gained 6 new, permanent 38 gallon receptacles during the same two month period. These growing numbers prove that the program is working to get rid of more pharmaceutical waste in a safe, responsible manner.

Progress has been made in spreading the news and marketing plans. The Board's website links to the Your Life Iowa page which leads you to the Take Away Program and the Disposal Project.

6. Iowa Monitoring Program for Pharmacy Professionals (IMP3) Update

Director Funk provided a program update. The last meeting was September 7, 2022, and the next meeting is scheduled for December 7, 2022.

Total program participants: 17

7. Compliance Update

Maggie Phelps provided a compliance update. Since September 1, 2022, some of the items that compliance staff have been working on are facilitation of division wide implementation of legislative bills, NABP review of DSCSA, IPA Annual Meeting, NASCSA Counterfeit Drugs, APPE Preceptor Showcase, NASCSA Annual Meeting, and FDA Webinar – Regulation of Preventative Vaccines.

- Inspections completed from September 1, 2022 to October 31, 2022 total 42.
- Controlled Substance Act inventory verification for inspection total 14.

8. Well-being Index for Pharmacy Personnel Reports

Informational Item.

Rules and Legislation

1. Proposed for adoption to amend Chapter 23, "Care Facility Pharmacy Practice," to provide a timeframe for a care facility to submit documentation to the provider pharmacy relating to the administration of vaccines provided by the pharmacy for an immunization or screening program (ARC 6421C)

Motion by Dane Nealson, second by Erik Maki, to adopt. Motion passed unanimously with Joan Skogstrom being absent for the vote.

2. Proposed for adoption to amend Chapter 41, "Outsourcing Facilities," to provide more detailed application information relating to the inspection requirement provided in Iowa Code; clarification on when a change of ownership is determined to have occurred, necessitating a license change; assessment of late penalty fees when an outsourcing facility is not timely in submitting a license change application; and assessment of a fee for written verification of a license (ARC 6422C)

Motion by Dane Nealson, second by Erik Maki, to adopt. Motion passed unanimously with Joan Skogstrom being absent for the vote.

3. Proposed for adoption to amend Chapter 14, "Public Information and Inspection of Records," to update the manner in which records are maintained by the Board and correct Iowa Code references (ARC 6423C)

Motion by Sherill Whisenand, second by Dane Nealson, to adopt. Motion passed unanimously with Joan Skogstrom being absent for the vote.

4. Proposed for adoption to amend Chapter 12, "Precursor Substances," to provide updated application processes and correct a cross-reference (ARC 6424C)

- Motion by Dane Nealson, second by Sherill Whisenand, to adopt. Motion passed unanimously.
- 5. Proposed for adoption to amend Chapter 10, "Controlled Substances," to temporarily place one substance into Schedule V of the Iowa Controlled Substances Act (ARC 6425C)
 - Motion by Dane Nealson, second by Sherill Whisenand, to adopt. Motion passed unanimously.
- 6. Proposed for notice of intended action to amend Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 18, "Centralized Prescription Filling and Processing," Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," and Chapter 39, "Expanded Practice Standards," to implement changes to the Iowa Code during the 2022 legislative session relating to licensed nurses engaging in the practice of nursing pursuant to a pharmacist's order and the issuance of a prescription in the name of a school district to obtain a bronchodilator, a bronchodilator and spacer, or an opioid antagonist
 - Motion by Sherill Whiseand, second by Dane Nealson to file for Notice of Intended Action. Motion passed unanimously.
- 7. Proposed for pre-filing to amend Iowa Code sections 124.204, 124.210, 124.212, and 124B.2 to permanently place eight substances into Schedule I, one substance into Schedule IV, one substance into Schedule V, designate one substance as a precursor substance, and move 11 Schedule I substances from 124.204(9) to 124.204(4) in response to similar action taken by the federal Drug Enforcement Administration
 - Motion by Sherill Whisenand, second by Dane Nealson to approve the proposed pre-filing to Iowa Code sections 124.204, 124.210, 124.212 and 124B.2. Motion passed unanimously.

Closed Session

At 11:27 a.m., on a motion by Dane Nealson, second by Sherill Whisenand, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; pursuant to Iowa Code section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings; and pursuant to Iowa Code section 21.5(1)(f), to discuss the decision to be rendered in a contested case conducted according to the provisions of Iowa Code chapter 17A.

At 2:28 p.m., the Board returned to open session. In open session the following actions were taken:

1. August 24, 2022 Closed Session Minutes

Motion by Dane Nealson, second by Sherill Whisenand, to approve the closed session minutes from the August 24, 2022 meeting as presented. Motion passed unanimously.

2. Combined Statement of Charges, Settlement Agreement, and Final Order

Motion by Dane Nealson, second by Sherill Whisenand, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Motion passed unanimously.

- A. 2020-0158 Joseph Rashid, RPh, License 17525, Wever
- B. 2022-0115 Lombard Pharmacy, License 4606, Lombard, IL

3. Combined Statement of Charges, Settlement Agreement, and Final Order

Motion by Dane Nealson, second by Sherill Whisenand, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Jim Mennen abstained. Motion passed unanimously.

- A. 2022-0094 & 2022-0120 Hy-Vee Pharmacy 1031, License 516, Ames
- B. 2022-0144 Jenette Hunger, RPh, License 23080, Ottumwa

4. Settlement Agreement and Final Order

Motion by Dane Nealson, second by Sherill Whisenand, to approve the Settlement Agreements and Final Orders in the following cases. Motion passed unanimously.

- A. 2022-0007 Daniel Pharmacy, License 752, Fort Dodge
- B. 2022-0008 John Daniel, RPh, License 19184, Fort Dodge

5. Closed with No Further Action

Motion by Dane Nealson, second by Sherill Whisenand, to close with no further action the following investigative files in complaint numbers: 2022-0068, 2021-0271, 2021-0145, 2021-0271, 2018-0133, 2021-0142, 2022-0184, 2022-0142, 2021-0144, 2022-0167, 2022-0132, 2022-0133, 2022-0178, 2022-0179, 2022-0131, 2022-0166, 2022-0170, 2022-0143, 2022-0148, 2022-0150, 2022-0152, 2022-0153, and 2022-0137. Motion passed unanimously.

6. Closed with No Further Action

Motion by Dane Nealson, second by Sherill Whisenand, to close with no further action the following investigative files in complaint numbers: 2022-0116, 2022-0099, 2022-0118, 2022-0119, 2022-0182, 2022-0077, 2022-0127, and 2022-0128. Jim Mennen abstained. Motion passed unanimously.

7. Administrative Warning

Motion by Dane Nealson, second by Sherill Whisenand, to issue administrative warnings to the respondents in the following investigative files in complaint numbers: 2019-0007, 2018-0116, 2022-0140, 2022-0141, 2022-0164, 2022-0134, 2022-0145, 2022-0147, 2022-0149, 2022-0151, 2022-0154, 2022-0155, 2022-0156, 2022-0157, 2022-0158, 2022-0159, 2022-0160, and 2022-0161. Motion passed unanimously.

8. Letter of Education

Motion by Dane Nealson, second by Sherill Whisenand, to issue letters of education to the respondents in the following investigative files in complaint number: 2022-0129 and 2022-0163. Motion passed unanimously.

At 2:35 p.m., motion by Dane Nealson, second by Sherill Whisenand, to adjourn. Motion approved unanimously.

Amanda Woltz, Administrative Assistant and Recording Secretary

Andrew Funk

Executive Director

Kathy Stone **Board Chair**

Kathryn SStone

APPROVED THIS DAY OF JANUARY 10, 2023